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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/729,340

12/04/2003

Dirk Jager

LUD-5793.1 CIP

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07/20/2007

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

07/20/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|  |  |   |  |
|--|--|---|--|
| <p align="center"><b>Advisory Action</b><br/><b>Before the Filing of an Appeal Brief</b></p> | <p><b>Application No.</b><br/>10/729,340</p> | <p><b>Applicant(s)</b><br/>JAGER ET AL.</p> |  |
|  | <p><b>Examiner</b><br/>Mark Halvorson</p>    | <p><b>Art Unit</b><br/>1642</p>             |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 30 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because:
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 13 and 92.  
Claim(s) objected to: 115.  
Claim(s) rejected: 58-60, 85 and 86.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because:

It is noted that the May 30, 2007 amendment was erroneously not entered.

It is noted that the after-response amendment filed May 30, 2007 indicated that claim 58 has been amended. However, there were no amended claims submitted with the after final submission. Please clarify whether a claim set was submitted with the May 30, 2007 after final submission.

Objections to Claims maintained.

The objection to claim 115 for having amino acid sequences without a SEQ ID NO: is maintained. Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Any peptide sequence with four or more amino acids must be identified with a SEQ ID NO:. Applicants may obviate this rejection by deleting the amino acid sequences and identifying the sequence by language such as "amino acids 158-167 of SEQ ID NO:32". Applicants must also delete the amino acid sequences in the specification or provide a SEQ ID NO: for these sequences.

35 USC § 112 1st paragraph rejections maintained

The rejection of claims 58-60 85 and 86 for failing to comply with the enablement requirement is maintained. Applicants argue that stimulation of T cells by MHC bound peptide is not necessary to practice the claimed invention and that there would not be undue experimentation to practice the claimed invention.

Applicant's arguments have been fully considered but they are not persuasive. For an invention to be enabled one of skill in the art must know how to make and use the claimed invention. One of ordinary skill in the art would not know how to use the claimed MHC binding peptides. The first step would be to find peptides that bind a MHC molecule. Given the vast number of MHC molecules and the lack of information on the critical amino acids necessary for a peptide to bind many of these MHC molecules this would be a formidable task. In addition, the function of an MHC binding peptide is to induce an immune response, which can be demonstrated by showing that an MHC binding peptide induces Ifn-g secretion from T cells. As previously stated, Wang et al disclose that finding a peptide that binds to a MHC molecule and stimulates an immune response is not a trivial matter. Finding a peptide that binds to a specific MHC molecule is only the first hurdle. The biggest hurdle is using the MHC binding peptide to generate cytolytic T cells against cancer cells. Applicants have not supplied any evidence that it would not be undue experimentation to generate MHC-binding peptides that would induce cytolytic T cells.


The rejection of claims 58-60 85 and 86 for failing to comply with the written description requirement is maintained. Applicant argues that one could present a list of all peptides which would satisfy the claim. Applicants contend that there are no numerical values that can be used to establish the "representative number" of examples. Furthermore, Applicants cite Falkner (Falkner v. Ingles 79 USPQ2d 1001) as support for their contention that there is no requirement for a connection between structure and function so as to satisfy the written description requirement.

Applicant's arguments have been fully considered but they are not persuasive. First of all one could not present a list of all peptides which would satisfy the claim. The potential list of MHC binding peptides is enormous consisting of every possible 9 to 25 amino acid peptide from the peptide of SEQ ID NO:32, a peptide of 1397 amino acids. In addition, the number of MHC molecules is enormous, many of which have no information on which amino acids are necessary for predicting binding peptides. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that Applicants were not in possession of the claimed genus.

Furthermore, Applicants have mischaracterized the holding in Falkner. The holding in Falkner states that: "in this case, accessible literature sources clearly provide, as of the relevant date, genes and their nucleotide sequences, satisfaction of the written description requirement does not require either the recitation or incorporation by reference".

Thus, Falkner holds that the requirement for a connection between structure and function so as to satisfy the written description requirement is not absolute and that there are instances when the specification does not have to demonstrate a connection between structure and function.

In the instant application, there is not sufficient information in the literature, prior to the filing date of the instant application, concerning the genus of MHC binding peptides of SEQ IN NO:32 to demonstrate that Applicants were in possession of the claimed genus of MHC binding peptides.

  
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